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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

HOFFMANN-LA ROCHE INC. and GENENTECH, INC., Plaintiffs, v. AIRIS PHARMA PRIVATE LIMITED Defendant.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** *Document Electronically Filed*

Plaintiffs Hoffmann-La Roche Inc. and Genentech, Inc. (collectively "Plaintiffs") for their Complaint against Defendant airis PHARMA Private Limited ("Airis") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Declaratory Judgment Act, Title 28 of the United States Code, 28 U.S.C. §§ 2201-02, and the patent laws of the United States, Title 35 of the United States Code, 35 U.S.C. § 1, *et seq*. It arises from Airis's filing of Abbreviated New Drug Application ("ANDA") No. 210169 with the United States Food and Drug Administration ("FDA"). Defendant Airis seeks FDA approval to engage in the commercial

manufacture, use, importation, offer for sale, and sale of an infringing generic version of the Plaintiff's pharmaceutical drug product Valcyte® (valganciclovir hydrochloride) 50 mg/mL for Oral Solution (the "Patented Drug") prior to the expiration of Plaintiffs' U.S. Patent No. 9,642,911 ("the '911 patent"). The Patented Drug is also protected by Plaintiffs' U.S. Patent No. 8,889,109 ("the '109 patent"). Collectively, the '911 and '109 patents are referred to herein as the "Patents-in-Suit".

PARTIES

2. Plaintiff Hoffmann-La Roche Inc. ("Roche") is a company organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424. Plaintiff Roche is the registered holder of approved New Drug Application ("NDA") No. 22-257 for the Patented Drug.

3. Plaintiff Genentech, Inc. ("Genentech") is a company organized and existing under the laws of the State of Delaware with its principal place of business at 1 DNA Way, South San Francisco, California 94080. Genentech is an exclusive licensee of the patents identified herein and commercializes the Patented Drug.

4. Upon information and belief, Defendant Airis is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 64 and 65, survey No. 342, Aleap Industrial Estate, Gajularamaram Village, Quthbullapur Mandal, Hyderabad, Telangana, India 500078.

5. Upon information and belief, Airis is in the business of making and selling generic pharmaceutical products, which it distributes, or intends to distribute, in the state of New York and throughout the United States.

6. Upon information and belief, Defendant Airis is seeking FDA approval to commercially market an infringing generic version of the Patented Drug.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Airis's website, available at http://www.airispharma.com/about, states that "airis PHARMA's vision is to develop generic formulation products for the US market…".

9. Airis's website, available at http://www.airispharma.com/contact, lists contact information for the United States at the following, (732) 686-5493 x100, telephone number, but no U.S. office address is provided.

10. Airis retained the New York firm of Blank Rome LLP, located at the Chrysler Building, 405 Lexington Avenue, New York, N.Y., 10174, and , in particular, has designated attorney Jay P. Lessler, Esq., of the Blank Rome LLP firm, jlessler@blankrome.com, (tel) (212) 885 5176, as its authorized agent to accept service of process for Airis in this matter.

11. Upon information and belief, on or about September 1, 2017, Airis directed that its afore-said counsel in New York prepare and transmit a letter to Plaintiff Genentech (Airis's "Paragraph IV Notice") styled as:

> Paragraph IV Patent Certification Notice regarding
> U.S. Patent No. 9,642,911
> airis Pharma Private Ltd.'s ANDA 210169
> for valganciclovir hydrochloride for oral solution (50 mg/mL)

12. Airis's Paragraph IV Notice states that Airis has sought FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of its generic copy of Plaintiffs' Patented Drug prior to expiration of Plaintiffs' '911 patent.

13. Upon information and belief, (i) Airis is in the business of manufacturing, marketing, importing, distributing, selling and offering to sell (collectively "commercially market") pharmaceutical drug products, including generic drug products, either directly or through its subsidiaries, agents, and/or alter-egos, and intends to commercially market an infringing generic version of the Patented Drug, throughout the United States and in this Judicial District; (ii) Airis purposefully has conducted business and continues to conduct business directly, and/or through its subsidiaries, agents, and/or alter egos in this Judicial District; and (iii) this Judicial District is likely a destination of Airis's generic drug products that are the subject of this lawsuit.

14. Upon information and belief, this Court has personal jurisdiction over Airis because, *inter alia*, Airis has conducted business in New York, Airis has availed itself of the privilege of conducting business in New York, Airis intends to commercially market its infringing generic drug products in the State of New York upon receiving FDA approval of ANDA No. 210169, and Airis has engaged in systematic and continuous contacts with the State of New York in connection with said ANDA and its Paragraph IV Notice.

15. In the alternative, upon information and belief, this Court has jurisdiction over Airis because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Airis is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Airis has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting its ANDA to the FDA, its Paragraph IV Notice and activities related thereto, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States.

16. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

17. On November 18, 2014, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '109 patent, entitled "Pharmaceutical Dosage Forms Comprising Valganciclovir Hydrochloride," to Roche as assignee of the inventors Maria Oksana Bachynsky, Martin Howard Infeld, and Navnit Hargovindas Shah. A copy of the '109 patent is attached hereto as Exhibit A.

18. Roche is the owner of all right, title and interest in the '109 patent.

19. Genentech is the exclusive licensee of the '109 patent.

20. On May 9, 2017 the USPTO duly and lawfully issued the '911 patent, entitled "Pharmaceutical Dosage Forms Comprising Valganciclovir Hydrochloride," to Roche as assignee of the inventors Maria Oksana Bachynsky, Martin Howard Infeld, and Navnit Hargovindas Shah. A copy of the '911 patent is attached hereto as Exhibit B.

21. Roche is the owner of all right, title and interest in the '911 patent.

22. Genentech is the exclusive licensee of the '911 patent.

ROCHE DRUG PRODUCT

23. Roche holds approved NDA No. 22-257 for the Patented Drug, sold under the trade name Valcyte® (hereinafter, "the Valcyte® NDA").

24. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '911 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to the Valcyte® NDA. Upon information and belief, the '109 patent is in the process of being submitted to the FDA for listing in the Orange Book in connection with the Valcyte® NDA.

AIRIS'S FDA SUBMISSION

25. Upon information and belief, Airis submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 335(j) (ANDA No. 210169), seeking approval to commercially manufacture, import, use, sell, and offer to sell an infringing generic version (the "Generic Product"), of the Plaintiff's Patented Drug.

26. Airis's ANDA No. 210169 relies upon the Valcyte® NDA and, according to Airis, allegedly contains the required data with respect to the bioavailability or bioequivalence of the Generic Product in comparison to the Patented Drug covered by the Valcyte® NDA.

27. 35 U.S.C. § 271(e)(2) states, in relevant part: "It shall be an act of infringement to submit … an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act … for a drug claimed in a patent or the use of which is claimed in a patent …if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug … claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

28. On or about September 1, 2017, Airis's New York counsel transmitted Airis's Paragraph IV Notice to Plaintiff Genentech, which states that Airis included a certification in its FDA submission under Section 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetics Act to obtain approval to engage in the commercial manufacture, use, or sale of Airis's infringing Generic Product before the Orange Book-listed expiration date of the '911 patent, i.e. before December 11, 2027.

29. The '109 patent also has an expiration date of December 11, 2027. Therefore, because Airis seeks FDA approval to commercially market its Generic Product prior to December 11,

2027, Airis thereby seeks FDA approval to commercially market its infringing Generic Product prior to the expiration of both Patents-in-Suit.

30. Plaintiffs are filing this complaint within forty-five (45) days of receiving the Airis Paragraph IV Notice. Plaintiffs reserve all rights to challenge the sufficiency of Airis's ANDA No. 210169 and the Airis Paragraph IV Notice.

COUNT ONE: INFRINGEMENT OF THE '911 PATENT

31. Plaintiffs repeat and re-allege the allegations of paragraphs 1-30 as though fully set forth herein.

32. Airis's submission of ANDA No. 210169 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Patented Drug prior to December 11, 2027 constitutes infringement of one or more claims of the claims of the '911 patent under 35 U.S.C. § 271(e)(2)(A).

33. Unless enjoined by this Court, upon FDA approval, Airis will induce infringement of the '911 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Airis will intentionally encourage acts of direct infringement with knowledge of the '911 patent and knowledge that its acts are encouraging infringement.

34. Unless enjoined by this Court, upon FDA approval, Airis will contributorily infringe the '911 patent under 35 U.S.C. § 271(c). Upon information and belief, Airis has had and continues to have knowledge that the Generic Product is especially made or especially adapted for a use that infringes the '911 patent and that there are no substantial non-infringing uses for the Generic Product.

35. Airis's actions, including its reliance on the purported defenses and statements set forth in the Airis Paragraph IV Notice regarding the '911 patent, warrant a finding that this case is an

exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

36. Airis's actions, including its knowledge of the '911 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

37. Plaintiffs will be substantially and irreparably harmed if Airis's infringement of the '911 patent is not enjoined.

38. Plaintiffs do not have an adequate remedy at law.

COUNT TWO: INFRINGEMENT OF THE '109 PATENT

39. Plaintiffs repeat and re-allege the allegations of paragraphs 1-38 as though fully set forth herein.

40. Airis's submission of ANDA No. 210169 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Patented Drug prior to December 11, 2027 constitutes infringement of one or more of the claims of the '109 patent under 35 U.S.C. § 271(e)(2)(A)

41. Unless enjoined by this Court, upon FDA approval, Airis will directly infringe the '109 patent under 35 U.S.C. § 271(a).

42. Unless enjoined by this Court, upon FDA approval, Airis will induce infringement of the '109 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Airis will intentionally encourage acts of direct infringement with knowledge of the '109 patent and knowledge that its acts are encouraging infringement.

43. Unless enjoined by this Court, upon FDA approval, Airis will contributorily infringe the '109 patent under 35 U.S.C. § 271(c). Upon information and belief, Airis has had and continues

to have knowledge that the Generic Product is especially made or especially adapted for a use that infringes the '109 patent and that there are no substantial non-infringing uses for the Generic Product.

44. Airis's actions warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

45. Plaintiffs will be substantially and irreparably harmed if Airis's infringement of the '109 patent is not enjoined.

46. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request:

A) A judgment be entered that Airis has infringed or would infringe the asserted Patents-in-Suit;

B) A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 210169 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be any earlier than the expiration date of the asserted Patents-in-Suit, including any extensions;

C) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Airis, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from commercially manufacturing, importing, using, offering to sell, or selling the Generic Product within the United States, or importing the Generic Product into the United States, prior to the expiration of the asserted Patents-in-Suit;

D) If Airis commercially manufactures, imports, uses, offers to sell, or sells the Generic Product within the United States, or imports the Generic Product into the United States, prior to the expiration of the asserted Patents-in-Suit, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

E) A judgment that if Airis commercially manufactures, imports, uses, offers to sell, or sells the Generic Product within the United States, or imports the Generic Product into the United States, prior to the expiration of the asserted Patents-in-Suit, including any extensions, a judgment awarding a trebling of the damages pursuant to 35 U.S.C. § 284 as a result of Defendants' willful infringement of the '109 and '911 patents**;**

F) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

G) Costs and expenses in this action; and

H) Such further and other relief as this Court may deem just and proper.

Dated: October 13, 2017

Respectfully submitted,

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